I. Listing of claims

This listing of claims is being provided for the convenience of the Examiner. No amendments have been made herein.

Claim 1. (Currently amended) An oral dosage form comprising (i) an opioid agonist in releasable form and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist which is substantially not released when the dosage form is administered intact, such that the ratio of the amount of antagonist released from said dosage form after tampering to the amount of said antagonist released from said intact dosage form is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C wherein said agonist and particles of the sequestered opioid antagonist are interdispersed and are not isolated from each other in two distinct layers.

Claim 2. (Currently amended) An oral dosage form comprising (i) an opioid agonist in releasable form and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist which is substantially not released when the dosage form is administered intact, such that the ratio of the amount of antagonist released from said dosage form after tampering to the amount of said antagonist released from said intact dosage form is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C wherein said particles of the sequestered opioid antagonist ~~is in the form of multiparticulates~~ are individually coated with a sequestering material which substantially prevents release of the antagonist.

Claim 3. (Currently amended) An oral dosage form comprising (i) an opioid agonist in releasable form and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist which is substantially not released when the dosage form is administered intact, such that the ratio of the amount of antagonist released from said dosage form after tampering to the amount of said antagonist

released from said intact dosage form is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C wherein said antagonist is dispersed in a matrix comprising a sequestering material which substantially prevents the release of the antagonist.

Claim 4. (Currently amended) An oral dosage form comprising (i) an opioid agonist in releasable form and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist which is substantially not released when the dosage form is administered intact, such that the ratio of the amount of antagonist contained in said intact dosage form to the amount of said antagonist released from said intact dosage form after 1 hour is about 4:1 or greater, based on the in-vitro dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C wherein said agonist and particles of the sequestered opioid antagonist are interdispersed and are not isolated from each other in two distinct layers.

Claim 5. (Currently amended) An oral dosage form comprising (i) an opioid agonist in a releasable form; and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist which is substantially not released when the dosage form is administered intact, such that the amount of antagonist released from said intact dosage form after 1 hour is less than an amount bioequivalent to 0.25 mg naltrexone and the amount of said antagonist released after 1 hour from said dosage form after tampering is an amount bioequivalent to 0.25 mg naltrexone or more, said release based on the dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C, wherein said agonist and particles of the sequestered opioid antagonist are interdispersed and are not isolated from each other in two distinct layers.

Claim 6. (Currently amended) An oral dosage form comprising (i) an opioid agonist in a releasable form; and (ii) particles of a therapeutically active agent

consisting essentially of sequestered naltrexone or a pharmaceutically acceptable sat thereof which is substantially not released when the dosage form is administered intact, such that the amount of naltexone released from said intact dosage form after 1 hour is less than 0.25 mg and the amount of said naltrexone released after 1 hour from said dosage form after tampering is 0.25 mg or more, said release based on the dissolution at 1 hour of said dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37 degrees C, wherein said agonist and particles of the sequestered naltrexone are interdispersed and are not isolated from each other in two distinct layers.

Claim 7. (Currently amended) An oral dosage form comprising (i) a therapeuticically effective dose of an opioid agonist; and (ii) particles of a therapeutically active agent consisting essentially of a sequestered opioid antagonist, such that at 1 hour after oral administration, said dosage form releases not more than 25% of said antagonist, said dosage form providing analgesia and said released antagonist not affecting analgesic efficacy, wherein said agonist and particles of the sequestered antagonist are interdispersed and are not isolated from each other in two distinct layers.

Claim 8. (Currently amended) An oral dosage form comprising: (i) an opioid agonist in a releasable form; and an (ii) particles of a therapeutically active agent consisting essentially of opioid antagonist in substantially non-releasable form wherein said particles of the sequestered antagonist is ~~in the form of multiparticulates~~ are individually coated with a material that substantially prevents release of the antagonist.

Claim 9. (Currently amended) An oral dosage form comprising: (i) an opioid agonist in a releasable form; and an (ii) particles of a therapeutically active agent consisting essentially of opioid antagonist in substantially non-releasable form wherein said antagonist is dispersed in a matrix comprising a material that substantially prevents the release of the antagonist.

Claim 10. (Original) The oral dosage form of claim 1 wherein said ratio is 10:1 or greater.

Claim 11. (Original) The oral dosage form of claim 1 wherein said ratio is 50:1 or greater.

Claim 12. (Original) The oral dosage form of claim 1 wherein said ratio is 100:1 or greater.

Claim 13. (Original) The oral dosage form of claim 6 wherein said intact dosage form releases at least 0.025 mg naltrexone at 1 hour.

Claim 14. (Original) The oral dosage form of claim 1 wherein said intact dosage form provides at least an amount of antagonist bioequivalent to 0.025 mg naltrexone at 1 hour.

Claim 15. (Original) The oral dosage form of claim 5 wherein the amount of antagonist released after 1 hour from said tampered dosage form is an amount bioequivalent to 0.5 mg naltrexone or more.

Claim 16. (Original) The oral dosage form of claim 5 wherein the amount of antagonist released after 1 hour from said intact dosage form is an amount bioequivalent to 0.125 mg naltrexone or less.

Claim 17. (Original) The oral dosage form of claim 6 wherein the amount of antagonist released after 1 hour from said tampered dosage form is 0.5 mg naltrexone or more.

Claim 18. (Original) The oral dosage form of claim 6 wherein the amount of antagonist released after 1 hour from said intact dosage form is 0.125 mg naltrexone or less.

Claim 19. (Original) The oral dosage form of claim 1, wherein the opioid agonist is selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, buprenorphine, fentanyl and derivatives thereof, dipipanone, heroin, tramadol, etorphine, dihydroetorphine, butorphanol, levorphanol, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 20. (Original) The oral dosage form of claim 19, wherein the opioid agonist is selected from the group consisting of oxycodone, hydrocodone and pharmaceutically acceptable salts thereof.

Claim 21. (Original) The oral dosage form of claim 1, wherein the opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 22. (Original) The oral dosage form of claim 21, wherein the opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 23. (Original) The oral dosage form of claim 22, wherein the opioid antagonist comprises naltrexone or a pharmaceutically acceptable salt thereof.

Claim 24. (Original) The oral dosage form of claim 2, wherein the material comprises a cellulose polymer or an acrylic polymer that is insoluble in the gastrointestinal tract and impermeable to the opioid antagonist contained within the coating.

Claim 25. (Original) The oral dosage form of claim 24, wherein the cellulose polymer is selected from the group consisting of ethylcellulose, cellulose acetate,

cellulose propionate, cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, and mixtures thereof.

Claim 26. (Original) The oral dosage form of claim 24, wherein the acrylic polymer is selected from the group consisting of acrylic acid and methacrylic acid copolymers, methyl methacrylate copolymers, ethoxyethyl methacrylates, cyanoethyl methacrylate, poly(acrylic acid), poly(methacrylic acid), methacrylic acid alkylamide copolymer, poly(methyl methacrylate), polymethacrylate, poly(methyl methacrylate) copolymer, polyacrylamide, aminoalkyl methacrylate copolymer, poly(methacrylic acid anhydride), and glycidyl methacrylate copolymers.

Claim 27. (Original) The oral dosage form of claim 1, wherein the dosage form provides sustained-release of the opioid agonist.

Claim 28. (Original) The oral dosage form of claim 27, wherein the dosage form is a sustained-release tablet or a sustained-release capsule.

Claim 29. (Currently amended) The oral dosage form of claim 2 wherein said particles of the sequestered antagonist ~~multiparticulates~~ are in the form of inert beads coated with said antagonist and overcoated with said material.

Claim 30. (Currently amended) The oral dosage form of claim 2 wherein said particles of the sequestered antagonist ~~multiparticulates~~ are in the form of a granulation comprising said antagonist and said material.

Claim 31. (Currently amended) The oral dosage form of claim 2 wherein said particles of the sequestered antagonist ~~multiparticulates~~ are dispersed in a matrix comprising said opioid agonist.

Claim 32. (Currently amended) The oral dosage form of claim 2 wherein said particles of the sequestered antagonist ~~multiparticulates~~ are contained in a capsule with said opioid agonist.

Claim 33. (Original) The oral dosage form of claim 3 wherein said matrix is in the form of pellets.

Claim 34. (Original) The oral dosage form of claim 33 wherein said pellets are dispersed in a matrix comprising said opioid agonist.

Claim 35. (Original) The oral dosage form of claim 33 wherein said pellets are contained in a capsule with said opioid agonist.

Claim 36. (Original) The oral dosage form of claim 1 wherein said tampering is by crushing.

Claim 37. (Original) The oral dosage form of claim 27 wherein said tampering is in a manner as to obtain an immediate release of said agonist.

Claim 38. (Original) The oral dosage form of claim 1 wherein said tampering is to make the agonist available for inappropriate use.

Claim 39. (Original) The oral dosage form of claim 1 wherein said antagonist does not significantly affect analgesia provided by the agonist.

Claim 40. (Original) A method of decreasing the abuse of an opioid agonist in an oral dosage form, comprising incorporating said opioid agonist into a dosage form of claim 1.

Claim 41. (Currently amended) A dosage form comprising:

(a) an opioid agonist; and

(b) particles of a therapeutically active agent consisting essentially of naltrexone in a substantially non-releasable form; wherein the agonist and naltrexone are at least partially interdispersed.

Claim 42. (Original) The dosage form of claim 41 wherein the opioid agonist is oxycodone, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, salts thereof, or mixtures thereof.

Claim 43. (Original) The dosage form of claim 42 wherein the opioid agonist is oxycodone hydrochloride.

Claim 44. (Original) The dosage form of claim 42 wherein the opioid agonist is hydrocodone bitartrate.

Claim 45. (Original) The dosage form of claim 42 wherein the opioid agonist is hydromorphone hydrochloride.

Claim 46. (Original) The dosage form of claim 41 wherein at least part of the naltrexone is in a matrix.

Claim 47. (Original) The dosage form of claim 41 wherein at least part of the naltrexone is in a coated bead.

Claim 48. (Original) The dosage form of claim 41 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 15% by weight of the naltrexone *in vivo* after 36 hours.

Claim 49. (Original) The dosage form of claim 48 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 8% by weight of the naltrexone *in vivo* after 36 hours.

Claim 50. (Original) The dosage form of claim 49 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 1% by weight of the naltrexone *in vivo* after 36 hours.

Claim 51. (Original) The dosage form of claim 41 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 3% by weight of the naltrexone *in vivo* after 1 hour.

Claim 52. (Original) The dosage form of claim 41 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 1.0% by weight of the naltrexone *in vivo* after 1 hour.

Claim 53. (Original) The dosage form of claim 41 wherein the naltrexone in a substantially non-releasable form is adapted to release less than 0.5% by weight of the naltrexone *in vivo* after 1 hour.

Claim 54. (Currently amended) A dosage form comprising:

(a) an opioid agonist; and

(b) particles of a therapeutically active agent consisting essentially of an orally-bioavailable opioid antagonist in a substantially non-releasable form.

Claim 55. (Original) The dosage form of claim 54 wherein the agonist and antagonist are at least partially interdispersed.

Claim 56. (Original) The dosage form of claim 54 wherein the orally-bioavailable opioid antagonist is naltrexone, or a salt thereof.

Claim 57. (Original) The dosage form of claim 54 wherein the opioid agonist is oxycodone, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, or salts thereof or mixtures thereof.

Claim 58. (Original) The dosage form of claim 54 wherein at least part of the antagonist is in a matrix.

Claim 59. (Original) The dosage form of claim 54 wherein at least part of the antagonist is in a coated bead.

Claim 60. (Cancelled)

Claim 61. (Original) A method of treating pain comprising administering to a human patient a dosage form of claim 1.